

Remarks

In response to the Notice of Non-Compliant Amendment Under 37 C.F.R. § 1.121 dated April 7, 2008, applicants have amended the status identifier of claim 1 to indicate that claim 1 is currently being amended and are resubmitting the amendments and remarks filed on January 14, 2008. In view of the above amendments and the following remarks, reconsideration of the outstanding office action is respectfully requested.

This submission was accompanied by a Request for Continued Examination, a petition for extension of time, and an information disclosure statement. Because the Notice of Appeal was entered on June 13, 2007, and the January 13, 2008, deadline fell on a Sunday, this submission is timely. All fees should be withdrawn from Deposit Account 14-1138.

Claim 1 has been amended to recite higher stringency requirements (i.e., structural requirements of the claimed DNA molecule based on hybridization capability) as well as the presence of delta and tau subunits, with which the delta prime subunit form the clamp loader complex). The latter limitation finds descriptive support in the background of the invention at page 2, line 18 to page 3, line 31; Examples 24-26, which demonstrate delta prime cooperation with delta and tau subunits to form a functional clamp loader complex that cooperates with beta clamp and polymerase components to form a PolIII enzyme complex; and Example 30, which demonstrates the temperature optimum for the *Aquifex aeolicus* PolIII complex.

Claims 9 and 10 have been cancelled.

Claims 1, 2, 5, 7, 8, and 11-19 are pending. Claims 16-19 stand allowed.

The rejection of claims 1, 2, 5, and 7-15 under 35 U.S.C. §112 (first paragraph) for lack of written descriptive support is respectfully traversed.

The U.S. Patent and Trademark Office (“PTO”) maintains its position that the single species disclosed as SEQ ID NO: 126 (*Aquifex aeolicus* delta prime subunit), and clamp loader complexes formed therewith, does not provide descriptive support for the genus of clamp loader complexes as claimed. Applicants respectfully disagree.

Given the recitation of high stringency conditions in claim 1 (hybridization and wash conditions of 5X sodium citrate buffer and at a temperature of 65°C), persons of skill in the art would expect hybridizing nucleic acids to be structurally similar to the nucleic acid sequence of SEQ ID NO: 125, and that the encoded proteins would be structurally and functionally similar to the delta prime subunit of SEQ ID NO: 126. See *EnzoBiochem Inc. v.*

Gen-Probe Inc., 296 F.3d 1316, 1327, 63 USPQ2d 1609, 1615 (citing U.S. Patent and Trademark Office “Synopsis of Application of Written Description Guidelines” with approval). Given this rational expectation, persons of skill in the art would also expect related organisms (i.e., from bacterial genus *Aquifex*) to share functional and structural similarities, including similarities in the structure and function of individual genes and their encoded proteins.

Given the above, applicants respectfully submit that the present application provides written descriptive support for the claimed subject matter. Therefore, the rejection of claims 1, 2, 6-16 for lack of written description should be withdrawn.

The rejection of claims 1, 2, 5, and 7-15 under 35 U.S.C. §112 (first paragraph) for lack of enablement is respectfully traversed.

It is the position of the PTO that the specification does not provide sufficient guidance for making other delta prime subunits and using those subunits to form clamp loader complexes within the scope of the claims. Applicants respectfully disagree.

Because the application adequately describes the presently claimed genus, persons of skill in the art would be fully able to obtain other polynucleotides encoding other delta prime subunits within the claimed genus, express and recover the encoded delta prime subunits, and allow recovered delta prime subunits to assemble with delta and tau subunits into a clamp loader complex.

The present application provides the nucleotide sequence of *Aquifex aeolicus holB* (e.g., SEQ ID NO: 125) as well as the amino acid sequence of the encoded delta prime subunit (e.g., SEQ ID NO: 126). The present application also describes how one of ordinary skill can isolate homologs of the disclosed sequence (see page 41, line 9 to page 42, line 29; Example 20), express the delta prime subunit (see Example 20), test the encoded delta prime subunit for clamp loader assembly competence (see Examples 24 and 25), and test the assembled clamp loader for activity (see Examples 26 and 30). Thus, one of ordinary skill in the art would have been fully able to make and use other delta prime subunits and assembled clamp loader complexes within the scope of the presently claimed invention.

In view of all of the foregoing, applicants submit that the rejection of claims 1, 2, 5, and 7-15 for lack of enablement is improper and should be withdrawn.

In view of all of the foregoing, applicant submits that this case is in condition for allowance and such allowance is earnestly solicited. The Commissioner is hereby authorized to charge any required fees to Deposit Account No. 14-1138.

Respectfully submitted,

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